K103677

510(K) SUMMARY

JAN 3 1 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: _____.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 8188 5604
Fax: +86 755 2658 2680

Contact Person:
Zhai Pei
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: October 18, 2010

2. Device Name: M7/M7T Diagnostic Ultrasound System

Classification
Regulatory Class: II
Review Category: Tier II
21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)
21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

M7/M7T Diagnostic Ultrasound System is a general purpose, portable/mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, PW-Mode, CW mode, Color-Mode, Color M-Mode, Power/Dirpower Mode, TDI mode or the combined mode (i.e. B/M-Mode).This system is a Track 3 device that employs an array of probes that include linear array, convex array

and phased array with a frequency range of approximately 2.5 MHz to 10.0 MHz.

4. Intended Use:

The M7/M7T Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetric, abdominal, pediatric, small parts (breast, testes, thyroid), neonatal cephalic, transcranial, cardiac, transvaginal, transrectal, peripheral vascular, urology, orthopedic, and musculoskeletal (conventional and superficial) exams.

5. Comparison with Predicate Devices:

M7/M7T Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1	Mindray	M7/M7T	K100830
2	Mindray	DC-7	K101041
3	GE	VIVID 7	K060542
4	Philips	iU22	K093563
5	Siemens	Acuson CV70	K050240
6	SonoSite	SonoSite MicroMaxx	K053069
7	Siemens	SEQUOIA	K072365
8	GE	LOGIQ E9	K092271
9	GE	Voluson E8	K061682
10	GE	Logiq E	K091374

They have the same technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate devices.

6. Non-clinical Tests:

M7/M7T Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: UD 2, UD 3, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37,IEC 62304,UL 60601-1, ISO14971 and ISO 10993-1.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the M7/M7T Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709-3995

JAN 31 2011

Re: K103677
Trade/Device Name: M7/M7T Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: January 14, 2011
Received: January 19, 2011

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the M7/M7T Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C5-2s	P4-2s	L7-3s
V10-4s	P7-3s	L12-4s
V10-4Bs	4CD4s	L14-6Ns
7L4s	6C2s	P12-4s
L14-6s	7L5s	CW2s

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known):

Device Name: M7/M7T Diagnostic Ultrasound System

Indications For Use:

The M7/M7T Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in gynecology, obstetric, abdominal,pediatric, small parts (breast, testes, thyroid), neonatal cephalic, transcranial, cardiac,transvaginal, transrectal, peripheral vascular, urology, orthopedic, and musculoskeletal(conventional and superficial) exams.

Prescription Use ___X____ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: N/A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1,2,3,4,6,7,8
	Abdominal	P	P	P	P	P	P	Note 1,2,3,4,5,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1,2,3,4,5,6,7,8
	Small organ(specify)**	P	P	P		P	P	Note 1,2,4,6,7,8
	Neonatal Cephalic	P	P	P	P	P	P	Note 1,2,4,5,6,7,8
	Adult Cephalic	P	P	P	P	P	P	Note 1,2,4,5,6,7,8
	Trans-rectal	P	P	P		P	P	Note 1,2,4,6,7,8
	Trans-vaginal	P	P	P		P	P	Note 1, 2,4,6,7,8,
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P	P	P	P	Note 1,2,4,5,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2,4,6,7,8
	Intravascular							
	Other (specify)***	P	P	P		P	P	Note 1, 2, 4,6,7,8
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1,2,5,6,7,8
	Cardiac Pediatric	P	P	P	P	P	P	Note 1,2,5,6,7,8
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indiçations for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: C5-2s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Abdominal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: V10-4s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Trans-vaginal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***	P	P	P		P	P	Note 1, 2, 4,6,7,8
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102677

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: V10-4Bs

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Trans-vaginal	P	P	P		P	P	Note 1, 2, 4,6,7,8
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***	P	P	P		P	P	Note 1, 2, 4,6,7,8
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: 7L4s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	P	Note 1,2, 4,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7,8
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P		P	P	Note 1,2, 4,6,7,8
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: L14-6s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note 1,2, 4,6,7,8
	Small organ(specify)**	P	P	P		P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P		P	P	Note 1,2, 4,6,7,8
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P		P	P	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	P	P	P		P	P	Note 1,2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: P4-2s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PW D	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Adult Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Cardiac Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,7,8
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: P7-3s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	Note 1, 2,5,6,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,8
	Small organ(specify)**							
	Neonatal Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,8
	Adult Cephalic	P	P	P	P	P	P	Note 1, 2,5,6,8
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	P	P	P	P	P	P	Note 1, 2,5,6,8
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1, 2,5,6,8
	Cardiac Pediatric	P	P	P	P	P	P	Note 1, 2,5,6,8
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: 4CD4s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note1,2, 3, 4,6,8
	Abdominal	P	P	P		P	P	Note1,2, 3, 4,6,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	Note1,2, 3, 4,6,8
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Prescription USE (Per 21 CFR 801.109)

008-10

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: 6C2s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N	Note 1, 2, 4,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1, 2, 4,6,7,8
	Small organ(specify)**							
	Neonatal Cephalic	N	N	N		N	N	Note 1, 2, 4,6,7,8
	Adult Cephalic	N	N	N		N	N	Note 1, 2, 4,6,7,8
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	N	N	N		N	N	Note 1, 2, 4,6,7,8
	Musculo-skeletal Superficial	N	N	N		N	N	Note 1, 2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	N	N	N		N	N	Note 1, 2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103627

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: 7L5s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1,2, 4,6,7,8
	Small organ(specify)**	N	N	N		N	N	Note 1,2, 4,6,7,8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	N	N	N		N	N	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	N	N	N		N	N	Note 1,2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	N	N	N		N	N	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: L7-3s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N	Note 1,2, 4,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1,2, 4,6,7,8
	Small organ(specify)**	N	N	N		N	N	Note 1,2, 4,6,7,8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	N	N	N		N	N	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	N	N	N		N	N	Note 1,2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	N	N	N		N	N	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription USE (Per 21 CFR 801.109) 510K K103627

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: L12-4s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	N	Note 1,2, 4,6,7,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1,2, 4,6,7,8
	Small organ(specify)**	N	N	N		N	N	Note 1,2, 4,6,7,8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	N	N	N		N	N	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	N	N	N		N	N	Note 1,2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	N	N	N		N	N	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103627

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: L14-6Ns

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	Note 1,2, 4,6,7,8
	Small organ(specify)**	N	N	N		N	N	Note 1,2, 4,6,7,8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional	N	N	N		N	N	Note 1,2, 4,6,7,8
	Musculo-skeletal Superficial	N	N	N		N	N	Note 1,2, 4,6,7,8
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular	N	N	N		N	N	Note 1,2, 4,6,7,8
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: P12-4s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PW D	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N	N	N	N	Note 1, 2,5,6,8
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	Note 1, 2,5,6,8
	Small organ(specify)**							
	Neonatal Cephalic	N	N	N	N	N	N	Note 1, 2,5,6,8
	Adult Cephalic	N	N	N	N	N	N	Note 1, 2,5,6,8
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult	N	N	N	N	N	N	Note 1, 2,5,6,8
	Cardiac Pediatric	N	N	N	N	N	N	Note 1, 2,5,6,8
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System: M7/M7T Diagnostic Ultrasound System

Transducer: CW2s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PW D	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)*							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric				N			
	Small organ(specify)**							
	Neonatal Cephalic							
	Adult Cephalic				N			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)***							
Cardiac	Cardiac Adult				N			
	Cardiac Pediatric				N			
	Intravascular (Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-Cardiac							
Peripheral Vascular	Peripheral Vascular							
	Other (specify)							

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments:Combined modes: B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Amplitude Doppler

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103677

Prescription USE (Per 21 CFR 801.109)